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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/816,846	03/23/2001	Charles Joel Arntzen	P00245USE	7468

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SUITE 3200
DES MOINES, IA 50309-2721

EXAMINER

HELMER, GEORGIA L

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 07/02/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n No.

09/816,846

Applicant(s)

ARNTZEN ET AL.

Examiner

Georgia L. Helmer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 April 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 73-77 is/are pending in the application.
- 4a) Of the above claim(s) 1 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 73-77 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. The Office acknowledges receipt of Applicants Response; dated 7 April 2003, paper number 7.
2. Applicant has amended claim 73. Applicant has withdrawn claim 1. Claims 1 and 73-77 are pending. Claims 73-77 are examined in this Office Action.
3. This action is made FINAL necessitated by Applicant's amendment.
4. All rejections not addressed below have been withdrawn.
5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
6. The Office acknowledges receipt and entry of Applicant's Terminal Disclaimer with respect to US 5,612,487 and US 6,034,298.

Specification

7. The Office has notified Applicant on 23 April 2001 that a substitute specification in compliance with 37 CFR 1.52 is required because the papers contain improper margins. It is further noted that to date no substitute specification has been received by the Office.

A substitute specification filed under 37 CFR 1.125(a) must only contain subject matter from the original specification and any previously entered amendment under 37

CFR 1.121. If the substitute specification contains additional subject matter not of record, the substitute specification must be filed under 37 CFR 1.125(b) and must be accompanied by: 1) a statement that the substitute specification contains no new matter; and 2) a marked-up copy showing the amendments to be made via the substitute specification relative to the specification at the time the substitute specification is filed.

Accordingly, Applicant is required to submit a substitute specification.

Claim Rejections - 35 USC § 112-second

8. Claims 76-77 remain rejected under 35 U.S.C. 112-2nd, for reasons of record.

In Claims 76 and 77, "derived from" is unclear, because it is unclear what is retained in the derived product.

Applicant traverses, stating primarily that claims 76 and 77 specifically claim the particular virus the immunogen is being derived from, and that one of ordinary skill in the art would understand the term "derived from" to mean an immunogen being derived from a particular virus whereby the virus possesses an antigen capable of eliciting an immune response and thereby the derived product retains the antigen, as taught by the specification.

Applicant's traversal has been considered and is unpersuasive because the claim needs to specify what of the starting material is retained in the product and what is left behind. Otherwise the metes and bounds of the claims are not defined. Applicant is using the term in question, "derived", in the definition of "derived", which is circular reasoning, and does not further clarify. It is suggested that "derived" be deleted.

Claim Rejections - 35 USC § 102

9. Claims 73-76 remain rejected under 35 U.S.C. 102b as being anticipated by Goodman, US 4,956,282.

Applicant traverses, stating primarily that Goodman does not anticipate because it does not teach (i) a transgenic plant expressing a recombinant viral antigen protein part.

Applicant's traversal has been considered and is unpersuasive because Goodman teaches the structural gene may be any mammalian gene of interest, which includes mammalian viral pathogen genes (column 3, lines 11-12). Goodman further teaches that antigens associated with viral pathogens, including the core and envelope proteins of leukemia and lyphotropic retroviruses, such as HTLA-I, -II, AND -III, feline leukemia virus, surface antigens of herpes simplex virus, hepatitis B virus, adenovirus " (column 3, lines 31-36).

Applicant traverses, stating primarily that Goodman does not anticipate because it does not teach (i) a transgenic plant expressing a recombinant viral antigen protein, (ii) whereby this protein is antigenic to a human or animal following administration of this protein either in an isolated purified form or as an ingestible transgenic plant or plant part.

Applicant's traversal has been considered and is unpersuasive because Goodman teaches that plants or plants may be harvested, and the desired product isolated for use (col 5, line 40-44), and that in some instances it is neither necessary or desirable to extract and isolate the protein product from the plant. Where the product can have a physiological effect on ingestion, it may be sufficient that the product be retained with the plant. This will be true *where the plant part is edible*, (col 5, lines 51-56), (emphasis added).

Applicant traverses, stating primarily that Goodman provides general disclosures means of expressing mammalian peptides in plant cells to achieve high yields, which may be harvested. The cited reference does not teach a specific means for expressing an immunogen derived from a viral protein in a plant.

Applicant's traversal has been considered and is unpersuasive because Applicant is arguing limitations not present in the claims. No specific means for expressing are set forth in the claims.

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Applicant traverses, stating primarily that Goodman does not teach the use of the proteins as a vaccine to the viruses.

Applicant's traversal has been considered and is unpersuasive because Applicant's arguments are not commensurate in scope with the claims. None of the claims recite proteins used as vaccine(s).

Remarks

10. No claim is allowed.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

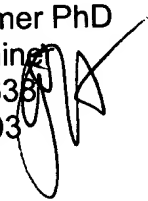
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12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Georgia L. Helmer whose telephone number is 703-308-7023. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 703-306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Customer Service, whose telephone number is 703-308-0196.

Georgia Helmer PhD
Patent Examiner
Art Group 1638
June 27, 2003




PHUONG T. BUI
PRIMARY EXAMINER
6/27/03